

A Journey of Differentiation



**BRANDED
FORMULATIONS**
India and UAE

~400,000

Our flagship brands, Insugen® and Basalog®, have cumulatively made a difference to nearly 400,000 diabetes patients in India since launch.

The launch of India's first indigenously developed and produced recombinant human Insulin, branded as Insugen®, marked the Company's successful foray into the branded formulations space in 2004. Today, we offer a wide portfolio of branded biosimilars, novel biologics and small molecule formulations to patients in India and UAE.

The growing burden of non-communicable diseases (NCDs) in the developing world has led to a widening of healthcare inequities. Patients with NCDs face several barriers to access that are related to affordability and availability as most of them pay out of pocket for essential medicines, which are often unavailable when needed. Each year, 15 million people between the ages of 30 and 69 years, die from one of the NCDs, and over 85% of these 'premature' deaths occur in low- and middle-income countries, according to the WHO.

For countries like India the NCDs burden is further magnified due to the lack of adequate public healthcare system and low per capita income which makes access to chronic therapies unaffordable for many. Having identified this challenge early on, Biocon chose to make a difference to patients in the Chronic therapy areas by developing high quality, advanced bio-pharmaceuticals leveraging its affordable innovation model and dovetailing it with its world class manufacturing capabilities.

A portfolio approach, focused on chronic disease segments such as diabetes, cancer, end-stage renal illnesses, immune disorders and other life-threatening conditions, enabled us to offer patients in India and UAE a wide portfolio of branded small molecule generics, biosimilars and novel biologics.

Beyond therapy, we support patients through disease awareness, prevention and management initiatives. We also assisted healthcare professionals and patients with the treatment of complex medical conditions. In the process, we built considerable brand equity and market leadership in the chosen therapeutic areas.

Making a Difference in Diabetes Management

When we started our pharma journey, India was home to the largest population of people with diabetes in the world. It was solely dependent on expensive imported insulins till the early 2000s resulting in poor access to this essential diabetes management therapy. In 2004, we successfully addressed this challenge by leveraging our expertise in fermentation technology to launch India's first indigenously developed and produced recombinant human Insulin (rh-Insulin), branded as Insugen®.

The availability of our affordable insulin in the market triggered a series of developments. Innovator insulins companies lowered the price of their products for India, the government gained the confidence to bring rh-Insulin under price control since it finally had a domestic solution. We thus made

a significant difference to diabetes management in the country, impacting a large patient pool, both directly as well as indirectly.

As the insulins market developed, doctors began graduating patients to modern insulin analogs. We introduced Basalog®, a long-acting insulin analog, in 2009 that allowed better metabolic control thereby resulting in an improved quality of life and treatment satisfaction for people with diabetes in India.

Introducing Patient-Friendly Devices

Continuing to spearhead the transformation of diabetes management in India, we decided to supplement our portfolio of insulin vials and refills with both reusable and disposable insulin delivery devices to maximize patient convenience.

Biocon launched INSUPen®, an affordable reusable insulin pen, in 2011 and Basalog



90,000+

Through our oncology portfolio we have served the needs of over 90,000 patients in India since launch.

One®, a pre-filled, disposable insulin pen, in 2015.

Improving the Diabetes Management Ecosystem in India

Today, we are one of the leading companies in the diabetology space in India with a wide basket of products across oral anti-diabetic drugs, rh-Insulin and Insulin Glargine. Our flagship brands, Basalog® and Insugen®, have cumulatively made a difference to the lives of ~400,000 patients in India since 2004. (Lancet report, IMS/IQVIA & CMARC data).

Basalog® is ranked as the No.2 Insulin Glargine brand in India, while Insugen® is positioned among the Top 3 brands of rh-Insulin. Insugen® and Basalog® reported combined sales of over ₹2 billion in FY19. (IMS/IQVIA).

Besides addressing the large need for affordable insulin therapy, we took the initiative to empower the medical ecosystem to efficiently address the needs of diabetes patients in the country. Our flagship patient outreach program, designed to sensitize and educate

people with diabetes on self-monitoring of blood glucose, exercise and dietary routines to maintain a healthy lifestyle, has proven to be highly effective. Our award-winning diabetes education initiative for medical practitioners is enhancing the understanding of the disease and its diagnosis and treatment to improve clinical outcomes.

Healing Heart Diseases

The strong correlation between diabetes and an increased risk of heart disease led Biocon to launch a dedicated Cardiology division in 2008 to leverage in-house R&D strengths for delivering cutting-edge products to treat cardiovascular diseases.

From cholesterol reducing agents such as BESTOR® and STATIX®, obesity management drugs like OLISAT® to ACTIBLOK™IPR for patients with hypertension and heart failure, our products widened the treatment scope for cardiologists, diabetologists and general physicians.

The Diabetology and Cardiology divisions were later merged to form the Metabolics division, which offers a complementary portfolio for holistic treatment of co-morbid diabetes, hypertension and dyslipidemia.

Crusading Against Cancer

Biocon entered the therapy space for cancer when the disease burden was posing a debilitating challenge for India, both socially and economically. At that time, the incidence of the deadly disease was alarmingly high.

In the early 2000s, the treatment paradigm for cancer was moving from small molecule cytotoxic chemotherapies to targeted therapies based on monoclonal antibodies and combinations thereof. Whilst India's generic industry had significantly brought down the cost of cytotoxic drugs, targeted drugs or



25,000+

Our biologic cancer therapies, BIOMAb EGFR®, CANMAb™ & KRABEVA® have benefited over 25,000 patient lives in India, so far.

biologics remained beyond the reach of most Indian cancer patients.

Biocon chose to invest in cutting-edge R&D to deliver affordable biologics that provide greater access to patients and thereby make a difference. The Oncotherapeutics division, set up in 2006, offered a comprehensive range of chemotherapy and supportive drugs.

We launched India's first novel monoclonal antibody Nimotuzumab in 2006 as BIOMAb EGFR® for the treatment of head & neck cancer. In 2010, we introduced Evertor™ as the first generic brand of Everolimus in India for the treatment of patients with advanced renal cell carcinoma. We also successfully developed and launched the world's first biosimilar Trastuzumab for patients of HER2-positive metastatic breast cancer in India as CANMAb™ in 2014. We expanded our portfolio in 2017 with KRABEVA®, a pan-cancer biosimilar Bevacizumab for patients suffering from metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers.

As one of India's leading oncology companies, Biocon has made noteworthy impact in cancer care through an affordable yet high quality mix of innovator, biosimilar and generic products. Our biologic cancer therapies

have benefited over 25,000 patient lives since 2006 (IPSOS, Internal data), and the division has cumulatively touched over 90,000* lives till date.

Offering Differentiated Products to Patients

The Branded Formulations business in India did not stop at bringing a niche portfolio of high-end therapeutics to patients, we also looked at innovative ways to ensure better patient compliance and convenience.

When we introduced two of our life-saving products, NUFIL Sf™ pre-filled syringes for Filgrastim and ERYPRO safe™ pre-filled syringes for Erythropoietin, in 2008 we incorporated them with an Ultrasafe Passive® Delivery System that enabled protection from needle stick injuries and offered enhanced patient comfort.

In 2014, we introduced CANMAb™ in a unique 150 mg multi-use vial whose availability allowed cancer patients to save money by buying smaller quantities as per their precise requirements, and storing the unused quantity for their next dose rather than wasting it. When used in conjunction with the standard 440 mg vial, the 150 mg presentation helped eliminate drug wastage and enabled additional savings for patients.

Patients using TBIS®, our brand of Tacrolimus ointment, benefited from a 36-month shelf life as compared to 24 months offered by competing products.

In 2017, we introduced KRABEVA® with an innovative temperature-sensitive packaging. The thermo-chromic stickers in the 'Qual Check' mechanism would change colour irreversibly if the cold chain temperature was not maintained within the prescribed range, thus ensuring the safety, purity and potency of the drug at the point of administration to the patient.

2,000+

CytoSorb®, a novel extracorporeal cytokine filter, has benefited over 2,000 patients in India so far.

Improving Treatment of Immunological Disorders

In 2013, we launched the world's first novel anti-CD6 monoclonal antibody, ALZUMAb™, which offered dermatologists in India the option of prescribing a 'first-in-class' biologic drug to treat acute psoriasis. A new treatment paradigm for patients, ALZUMAb™ offered a less aggressive dosing regimen and a longer treatment free period. It complemented our niche portfolio of oral and topical immunosuppressants to treat dermatological disorders such as psoriasis, atopic dermatitis and vitiligo.

Patients with skin disorders often have to face social ostracism in India. Through our key Immunotherapy brands such as TBIS®, PSORID® and CALPSOR® C we are today offering a better quality of life to these patients.

Caring for Patients of Kidney Disease

At a time when the incidence of chronic kidney disease (CKD) was rising in India, Biocon's Nephrology division offered patients one of the most comprehensive and cost-effective portfolio of therapies. At that time, less than 10% of all CKD patients in India received any kind of renal replacement therapy as these treatments were a low priority for the cash-strapped public hospitals. Also, the number of renal transplantations were woefully low at 3.25 per million population. (*Clinical Kidney Journal; Evolution of Kidney Transplantation in India*).

As one of the largest manufacturers of immunosuppressants in the world, we had the widest range of products for patients undergoing organ transplantation, coupled with affordable yet world class products for renal anemia management.

We introduced a range of specialty products in Nephrology, including Tacrograf™ (Tacrolimus), Renodapt® (Mycophenolate Mofetil) for transplant patients and ERYPRO safe™

(Erythropoietin) and BIONESPT™ (Darbepoetin) for anaemia management.

In 2013, we launched an in-licensed 'first in class' sepsis management therapy to enable physicians to treat critically ill patients. CytoSorb®, a novel extracorporeal cytokine filter for sepsis management helps remove excess cytokines that cause multi organ failure, has benefited over 2,000 patients since its launch.

These differentiated products have enabled Biocon to emerge among the leading players in the nephrology market and transplant segment in India.

Boosting Critical Care in India

Launched in 2010, Biocon's Critical Care division is playing a crucial role in the critical illness segment with a strong anti-infective portfolio, such as IVNEX™, PENMER™ and KOOLISTIN®. At a time when the infectious disease burden in India is rising, with life-threatening bacteria mutating into 'multi drug,' 'poly drug' resistant strains posing a major threat to overall disease management, our wide range of injectable antibiotics and plasma products are ensuring affordable access to life-saving therapies.

Strong Value Builder

The Branded Formulations business has been a strong value builder for Biocon. We have built considerable brand equity with doctors and patients over the years through our affordable and differentiated portfolio in challenging disease spaces. A combination of products, patients and physician support programs have enabled us to be a strong player in the therapeutic areas of diabetology, cardiology, oncology, immunology, nephrology and critical care.

**Note: The estimated patient reach numbers have been calculated indirectly based on volume supplied and certain assumptions related to dosage per patient, duration of treatment, units sold, internal data and market research reports.*

Branded Formulations UAE

In 2007, Biocon and Neopharma established NeoBiocon, a joint venture company headquartered in Dubai to provide affordable life-saving drugs to the people of UAE. A pioneering initiative, the joint venture aimed to provide niche, life-saving biopharmaceutical products in key therapeutic areas.

One of the fastest growing players in the region,

today, NeoBiocon ranks amongst the Top 15 pharmaceutical companies in UAE. It is the No. 1 generic company in UAE in the cardiovascular and diabetes markets, and is also ranked among the Top 3 generic companies in the country. *(IMS/IQVIA)*.

Supported by more than 40 brands across cardiovascular, diabetes, respiratory, acute, oncology and gastrointestinal therapy segments, its sales

are well diversified across branded generics, biosimilars and in-licensed novel products. The Top 10 brands contribute over 65% of sales. *(Internal Data)*.

Most of NeoBiocon's branded generic products are ranked among the Top 5 in their respective segments. Brand Statix (Atorvastatin) is at No. 2 in the UAE lipid management market and is among the Top 50 brands in the overall

UAE pharma market. *(IMS/IQVIA)*.

Biocon launched CANHERA, the first biosimilar Trastuzumab in UAE aimed at providing affordable access to patients suffering from breast cancer, in FY19. The launch of CANHERA represents Biocon's second biosimilar launch in the UAE market, having launched biosimilar Insulin Glargine under the brand name Glaricon® earlier.

BRANDED FORMULATIONS: FY19 at a Glance



Revenue

6,564

₹ Million

Growth 7%

In FY19, the Branded Formulations segment grew 7% to ₹6,564 million from ₹6,115 million, led by good growth in the India business, both in sales as well as profitability. The good performance in India was offset by a subdued performance of the business in UAE which was impacted by delays in product registrations with the local health authorities and repricing of branded generic

products by the Ministry of Health.

The Metabolics, Nephrology, Critical Care and Market Access divisions were the key growth drivers for the Branded Formulations - India (BFI) business. Key brands like Insugen®, Basalog®, ERYPRO™, TACROGRAF™ and PSORID™ reported strong double-digit growth. The Top 10 brands in our BFI portfolio grew 15% and

accounted for ~78% of total sales in FY19. As a specialty products company, 70% of our overall India business is now accounted for by biologics / biosimilars products.

In UAE, while newly launched branded generics, biosimilars and in-licensed products grew during the year, overall performance was impacted by certain external factors.

+ Read more on Branded Formulations Business : Page 139

Sources:

1. *Chronic Kidney Disease in India: Challenges and Solutions (S.K. Agarwal & R.K. Srivastava - Nephron Clin Pract, 2009)*
2. *Clinical Kidney Journal*